

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 00N-1440]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910-0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the "Prescription Drug User Fee Act of 1992" (PDUFA) (Public Law 102-571), as

amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Form FDA 3397 is the user fee cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's data base system, there are an estimated 208 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 1999. CDER estimates 2,478 annual responses that include the following: 125 new drug applications, 1,458 chemistry supplements, 755 labeling supplements, and 140 efficacy supplements. CBER estimates 443 annual responses that include the following: 8 biologics license applications, 396 manufacturing (chemistry) supplements, 29 labeling supplements, and 10 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of August 18, 2000 (65 FR 50540), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Form | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| FDA 3397 | 208 | 14.4 | 2,921 | .30 | 876 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 28, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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